



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

APR - 2 1999

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel
Rexall-Sundown
6111 Broken Sound Parkway, NW
Boca Raton, Florida 33487-3693

4448 '99 APR -7 19:53

Dear Ms. Trinker:

This is in response to your letter of March 15, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Rexall-Sundown is making the following claim, among others, for the product Sundown Herbals Brand Dong Quai: "Calcium promotes bone mass, helps reduce the risk of osteoporosis..."

This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis. The product Sundown Calcium, which is mentioned in the claim, may be eligible for the health claim in 21 CFR 101.72. However, if the product Sundown Herbals Dong Quai is not eligible to bear a calcium-osteoporosis health claim, references to it on its label would misbrand the dietary supplement under 21 U.S.C. 343(r)(1)(B).

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 264

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Florida District Office, Office of Compliance, HFR-SE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

HFV-232 (Brown)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-456:rjm4/2/99:docname:64224.adv:disc36



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Fax (561) 995-5188

March 15, 1999

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

3/17/99

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Dong Quai: Herbal support for women's special needs. For centuries, women around the world have benefited from Dong Quai's ability to help balance the female cycle and nourish the body through normal hormonal changes. To further support women's special needs, take this item with Sundown Soy and Sundown Calcium. Soy contains isoflavones which are helpful in maintaining bone health. Calcium promotes bone mass, helps reduce the risk of osteoporosis and also provides nutritional support during a woman's monthly cycle.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

A handwritten signature in cursive script, appearing to read "Deborah Shur Trinker".

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure